120

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Appeal to the Board of Patent Appeals and Interferences

PATENT APPLICATION

1654

In re PATENT APPLICATION of
Inventor(s): BEINDORFF ET AL
Appln. No.: 09 | 863,439
Series Code ↑ | Serial No. ↑

Group Art Unit: 1654
Examiner.: Coe
Atty. Dkt. 059490-5015 | P27598US
M# | Client Ref

Filed: May 24, 2001
Title: BLENDS OF URSOLIC ACID/OLEANOLIC ACID

Date: December 1, 2003

Commissioner of Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Customer Window
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Sir:

1. ☐ **NOTICE OF APPEAL**: Applicant hereby appeals to the Board of Patent Appeals and Interferences from the decision (not Advisory Action) dated _____ of the Examiner twice/finally rejecting claim(s) in this application or in this application and its parent application.
2. ☒ **BRIEF** on appeal in this application attached in triplicate (extendable up to 5 months).
3. ☐ An **ORAL HEARING** is respectfully requested under Rule 194 (due two months after Examiner's Answer- unextendable)
4. ☐ Reply Brief is attached in triplicate (due two months after Examiner's Answer – unextendable).
5. ☐ "Small entity" statement filed: ☐ herewith. ☐ previously.

6. **FEE CALCULATION**

		Large/Small Entity		Fee Code
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If box 2 above is X'd, ... enter		$330/165	$330	120/220
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7. Original due date: June 30, 2003				
8. Petition is hereby made to extend the original due date	(1 mo)	$110/$55		115/215
to cover the date this response is filed for which the	(2 mos)	$420/$210		116/216
requisite fee is attached.	(3 mos)	$950/$475		117/217
	(4 mos)	$1,480/$740		118/218
(Usable only if box 2 is X'd--- 5 mos)		$2,010/1,005	+$2,010	2,010 128/228
10. Enter any previous extension fee paid ☐ previously since above Original due date (item 8); ☐ with concurrently filed amendment.....			-$0	
9. **Subtract line 9 from line 8 and enter: Total Extension Fee**				+$
10. **TOTAL FEE ATTACHED =**				$2,340

(Our Deposit Account No. 50-0310)
(Our Order No. 059490 | 5015
C# | M#

CHARGE STATEMENT: The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (missing or insufficiencies only) now or hereafter relative to this application and the resulting Official Document under Rule 20, or credit any overpayment, to our Accounting/Order Nos. shown above, for which purpose a duplicate copy of this sheet is attached.
This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal sheet is filed.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

BEINDORFF ET AL

Serial No.: 09/863,439

Group Art Unit: 1654

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Title: BLENDS OF URSOLIC ACID/ OLEANOLIC ACID

APPELLANTS' APPEAL BRIEF

Commissioner for Patents
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Sir:

Introduction

The invention on appeal relates to certain blends of one or more glycerides and a mixture of ursolic acid and oleanolic acid extracted from fruit skins for use in food products or as food supplements.

Ursolic acid and oleanolic acid extracted from fruit skins have previously been proposed for use in foods because of their beneficial health effects . However, despite the health advantages in using these acids, such use has been severely restricted because of the undesirable off taste of the acid extracts. The appellants have found that this is due, not to the acids themselves but to the presence of natural apolar and low molecular weight components associated with the acids as extracted from the fruit skins. Accordingly, the appellants have found that by reducing the amount of these components, off taste normally associated with the acids isolated from fruit skins is eliminated, thus making it possible to effectively obtain the health benefit of the acids without the undesirable off taste previously encountered.

(1) Real Party in Interest

The real party in interest is Loders Croklaan B.V. of the Netherlands by virtue of assignment recorded on September 26, 2001 on Reel 012186, Frame 0464.

(2) Related Appeals and Interferences

There are no appeals or interferences known to appellants, the appellants' legal representatives or assignee, which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

(3) Status of Claims

Claims 1-23 have been presented in this application. Claims 3, 4, 15 and 16 have been canceled. Claims 1, 2, 5-14 and 17-23 are pending in the case and are involved in this appeal.

The claims on appeal (claims 1, 2, 5-14 and 17-23) are set forth in the Appendix to this brief.

(4) Status of Amendments

The appellants have filed two amendments after final rejection. These amendments were filed on March 31, 2003 and June 25, 2003. Both amendments have been entered. See Examiner's Advisory Actions dated April 17, 2003 and July 21, 2003.

(5) Summary of the Invention

As noted earlier, the invention is concerned with blends of one or more glycerides and a mixture of ursolic acid and oleanolic acid isolated from fruit skins which are free from the off taste normally associated with the use of ursolic acid and oleanolic acid isolated from fruit skins. The invention is based on the appellants' discovery that the undesirable off taste previously encountered in the use of these acids as isolated from fruit skins is not due to the acids themselves but is caused by the presence of natural apolar and/or low molecular weight components (¶ bridging pages 1-2 of the appellants' specification). The appellants have found that if the content of apolar and/or low molecular weight components in the mixture of ursolic acid and oleanolic acid extracted from fruit skins is reduced to less than 20 wt % of the amount of these

components present in the natural extracts, the undesired off taste is avoided. See appellants' specification, page 2, first full ¶.

Of the claims at issue, claim 1 is the only independent claim, the remaining claims being dependent, directly or indirectly, on claim 1.

Claim 1 defines the invention in its broadest terms as a blend of (1) a mixture comprising ursolic acid and oleanolic acid isolated from fruit skins and containing less than 20 wt % of the natural apolar and/or low molecular weight components in a natural extract from fruit skins and (2) 5-80% by weight of one or more glycerides having a specified solid fat content. See page 3, lines 1-12 of appellants' specification.

Claim 2 specifically refers to the natural apolar or low molecular weight components which appellants have found cause the off taste in the natural extract, i.e. hydrocarbons, alcohols, fatty acids, triglycerides, ketones and carbohydrates. See page 2, lines 25-28 of appellants' specification.

Claim 5 defines a preferred blended composition according to the invention comprising, as a component A, the blend of glyceride and mixture of ursolic acid and oleanolic acid as defined in claim 1 with, as a component B, a solid fat with an N20 of more than 20 and optionally, as component C, a fat of at least 40 wt % of 18 C-atoms fatty acid with 1-3 double bonds in specific amounts. See the appellants' specification at page 3, last full ¶ and page 4, lines 1-6.

Desirably component B is, for example, palm oil, a palm oil fraction, hardened palm oil, or the like. See claim 6 and the 1st full ¶, page 4 of the specification.

Component C is, for example, sunflower oil, olive oil or equivalent. See claim 7 and the specification at page 4, 2nd full ¶.

Isoflavones and flavones may also be advantageously included in the blends of the invention. See claim 8 and the ¶ bridging pages 4-5 of the specification, especially, page 5, lines 2-3.

Preferably the mixture of ursolic and oleanolic acid is isolated from the skins of apples, pears, cranberries, cherries or prunes. See claim 9 and the specification at page 6, lines 3-5.

The blend is desirably used as the fat phase of a food product which may be, for example, mayonnaise, sauces or the like. See claims 10, 11 and the full ¶, page 5 of the specification. These food products may include a continuous fat phase comprising 10-90 wt % of the product. See claim 12 and again the full ¶, page 5 of the specification.

The invention also contemplates food supplements where the claimed blend is encapsulated. See claims 13, 14 and the specification at page 5, lines 23-27.

Preferred ratios of ursolic acid to oleanolic acid and upper limits on the amount of undesired natural apolar or low molecular weight components are set out in claims 17 and 18. See also the full ¶, page 2 of the specification.

Other preferred embodiments of the invention relating to the nature of the glyceride part of the blend, component B and relative amounts of components A, B and C are set out in claims 19-23 and in the specification at page 3, lines 7-12; lines 26-27 and page 4, lines 1-6.

The Issue

The Examiner has rejected all of the appellants' claims under 35 U.S.C. 103(a) as unpatentable over U.S. Patent 5,948,460 (the '460 patent) in view of U.S. Patent 4,752,606 (the '606 patent) and SU 827066 (SU '066).

The basic issue for consideration, therefore, is whether or not the Examiner's Section 103(a) rejection is correct. The appellants submit, for reasons discussed hereafter, that the Examiner's Section 103(a) rejection is incorrect and should be reversed.

Grouping of Claims

The Examiner has grouped all of the claims together in the Section 103(a) rejection. No effort has been made by the Examiner to deal with any of the specific features of the appellants' dependent claims. The appellants consider that all claims should be found allowable because the single independent claim (claim 1) defines subject matter which is not obvious from the cited art. However, it is also submitted that the dependent claims are separately patentable over the references because there is no

suggestion in the references of the specific features of the dependent claims, at least in the context of anything resembling claim 1.

Appellants' Argument

The appellants submit that the Examiner's Section 103(a) rejection should be reversed.

The appellants' reasoning as to why the Examiner's rejection should be reversed can be briefly summarized as follows:

(1) None of the references is concerned with the problem of off taste presented by ursolic acid and oleanolic acid isolated from fruit skins. The references, considered singly or together, cannot, therefore, make obvious the appellants' solution to a problem which is not dealt with in the references;

(2) There is no motivation in the art to combine the references relied on by the Examiner to make the rejection. Even putting aside the fact that the references are not concerned with the off taste problem of concern to the appellants, there is no reason to select purified ursolic acid obtained according to SU '066 and purified oleanolic acid from the '606 patent to use together in the compositions of the '460 patent when the '460 patent itself teaches that ursolic acid and oleanolic acid can be used separately, in purified or crude extract form, for a purpose fundamentally different from the appellants' purpose; and

(3) Even if the references are combined as the Examiner proposes, when there is no valid reason to do so, the appellants' compositions are not obtained because none of the references discloses or suggests compositions including any glyceride component, much less the specific type of glyceride component called for in appellants' claims.

Referring more specifically to the Examiner's references, it is noted that the '460 patent discloses the addition of one or more compounds selected from oleanolic acid, ursolic acid and plygodial to a flavored product, particularly a diet drink, containing an artificial sweetener, to reduce the aftertaste caused by the use of the artificial sweetener. The additive may be used as a purified product or as a crude extract from plants (see Col. 4, lines 11-15 of the '460 patent).

While '460 is concerned with the undesirable aftertaste caused by artificial sweeteners, the patent says nothing about the undesirable off taste which is known to be introduced into compositions when using plant extracts of ursolic acid and oleanolic acid for health effects. Since the '460 patent is not concerned with the appellants' problem, the patent cannot suggest the appellants' solution to the problem or make the solution obvious to one in the art. Furthermore, the '460 patent indicates that the additive used therein can be in purified form or as a crude extract. This hardly can be viewed as suggesting that off taste could be avoided by using purified acids as the Examiner's rejection presupposes.

It is also noted that the '460 patent makes no reference at all to the use of a glyceride component. A glyceride of the type specifically defined in claim 1 is an essential component of the appellants' invention.

The '606 patent relates to pharmaceutical compositions which contain oleanolic acid for treating ulcerogenic disorders. The patent does not disclose the use of ursolic acid with oleanolic acid. The oleanolic acid used in the '606 patent may be obtained by extraction from plants, e.g. grape husks (see Col. 5, lines 1-3 and Example 1). There is no teaching in the '606 patent to use mixtures of ursolic acid and oleanolic acid in any way, much less with a glyceride as required for by the appellants' claims. Furthermore, there is nothing in the '606 patent to indicate that there would be any ursolic acid with the oleanolic acid when the latter is extracted. Additionally, there is nothing in the references to indicate any off taste problem with oleanolic acid or any solution to such problem.

The same is true for SU '066. This reference describes the preparation of ursolic acid by extraction from catmint. There is no reference in SU '066 to oleanolic acid or any indication that such acid would be present in a catmint extract in admixture with the ursolic acid. Furthermore, as in the case of the other references, there is no mention of a problem of off taste in extracts of ursolic acid and oleanolic acid in SU '066 or any solution to such problem.

There is also no disclosure in SU '066 to use the ursolic acid with any kind of glyceride, much less one as called for by the appellants.

The appellants submit, for reasons evident from the foregoing discussion of the references, that the present invention is not obvious from the references, particularly

since none of the references is concerned with the appellants' problem or suggests the solution thereto.

Furthermore, taking into account the nature of the reference teachings, there is no motivation in the art which would warrant the Examiner's reference combination. In any case, however, the appellants' invention as defined in claim 1 cannot be reached, even if the references are combined as the Examiner has proposed, because the combination still fails to provide for the appellants' glyceride component.

Appellants' claim 2 underscores the deficiencies of the Examiner's references in that there is nothing in any of the references to indicate that reducing the amount of the specific materials recited in this claim would be useful to avoid any off taste in mixtures of ursolic acid and oleanolic acid isolated from fruit skins. For all that was known in the art, the extracted acids themselves could be the cause of the off taste which has previously limited the use of such acids.

The Examiner's rejection is based, in essence, on the view that the '460 patent discloses mixtures of ursolic acid and oleanolic acid in foods while the secondary references show, respectively, the purification of ursolic acid (SU '066) and oleanolic acid (the '606 patent). The Examiner states that SU '066 and U.S. '606 teach extracting the ursolic and oleanolic acid, respectively in the same manner as the appellants.[1] The Examiner concludes from this that the acids of the art would have the same characteristics as the acids in the appellants' compositions and that it would be obvious to use the acids of U.S. '606 or SU '066 in the compositions of U.S. '460 "because U.S. '606 and SU '066 "teach that their acids have a high purity content".

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[1] However, comparison of the appellants' examples with the reference procedures shows this is not the case. The respective procedures are different and there is no assurance from the secondary disclosures that the acid compositions they prepare would meet the restriction the appellants call for with respect to the content of natural apolar and low molecular weight components present in natural extracts from fruit skins. In fact, SU '066 obtains its ursolic acid by extraction of catmint, not fruit skins as called for by the appellants. In any case, it is of no consequence with respect to the present obviousness issue, whether or not the acids of the secondary references are processed in the same way. The key points are that there is no motivation to use the acids of the secondary references in the '460 invention and even if they are, the appellants' invention is not realized.

However, what the Examiner has overlooked is the fact that there is no suggestion in the art that the extracted acids of SU '066 or U.S. '606 even if they "have a high purity content" as the Examiner presumes would avoid the undesired off taste encountered with the prior art use of ursolic acid and oleanolic acid. The Examiner has erroneously presumed the prior art knew that the off taste of mixtures of ursolic and oleanolic acids extracted from fruit skins is due to impurities rather than the acid themselves. Thus, even if the extractions of the references somehow removed the offending natural and low molecular weight components which the appellants have found cause the off taste in the extracted acids, there is no reason to think that the acids of U.S. '606 and SU '066 would avoid off flavor. Moreover, there is no motivation in the art to use the acids of U.S. '606 or SU '066 in the compositions of U.S. '460, particularly since U.S. '460 indicates that the acids may be used therein in purified or unpurified form for its different purposes and none of the references is concerned with the off taste encountered with prior art extracts comprising ursolic acid and oleanolic acid.

Finally, as noted, even if the references can be combined as the Examiner proposed, there is nothing in the Examiner's references suggesting the blending of a mixture of ursolic acid and oleanolic acid as defined with 5 to 80 wt % of one or more components selected from mono-, di- and triglycerides with the glyceride part of the blend displaying a solid fat content measured by NMR-pulse on a non-stabilised fat at the temperature indicated of :

5 to 90 at 5°C
2 to 80 at 20°C and
less than 15 at 35°C.

The Examiner recognizes that U.S. '606 does not teach ursolic acid and that SU '066 does not teach oleanolic acid. Nevertheless, he concludes that it would be obvious to combine the oleanolic acid of U.S. '606 and the ursolic acid of SU '066 for use in the '460 patent. This is despite the fact that neither U.S. '606 nor SU '066 uses the combination of acids and neither of these references, nor the '460 patent, is concerned with the off taste of these acids or how to solve the problem of off taste. Furthermore, none of the references combines the appellants' mixture of acids with a glyceride component as the appellants require. There is, in short, clearly nothing in any of the references to suggest the combination of features representing the appellants' invention.

Manifestly, to support a Section 103(a) rejection, it is incumbent upon the Examiner to provide a reason why one having ordinary skill in the art would have been led to modify a prior art reference or to combine applied references to arrive at the claimed invention. The requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from knowledge generally available to one having ordinary skill in the art. *In re Fine*, supra; *Uniroyal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 USPQ2d 1434 (Fed. Cir. 1988); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F2d. 281, 227 USPQ 657 (Fed. Cir. 1985); *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 221 USPQ 929 (Fed. Cir. 1984); *In re Sernaker*, 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983). There is no such motivation here. The Examiner's combination is based purely on hindsight in the light of the appellants' disclosure. Furthermore, even if the references are combined, as the Examiner proposes, the appellants' compositions of claim 1, including the specified glyceride component, is not realized.

The foregoing comments are directly primarily towards showing the error in the Examiner's rejection of appellants' main claim 1. The Examiner has not attempted to show that the features of the remaining dependent claims are obvious from the art in the context of the broader invention represented by claim 1. However, specific features in the dependent claims provide a further basis for showing error in the Examiner's rejection of these claims. As noted earlier, claim 2, which specifies the nature of the materials causing the off taste, is not in any sense obvious from the references.

The references also do not suggest the specific combination of components A, B and C as called for in claim 5 and as more specifically required in claims 6, 7 and 8.

Similarly, there is no disclosure or suggestion of the specific features recited in the other dependent claims in the context of the invention defined by claim 1. Thus, while the isolation of ursolic acid and oleanolic acid from fruit skins is known, there is nothing in the art suggestive of what the appellants have done with such mixtures to provide for an effective way of using the same in foods and food supplements free from the prior art problem of off taste.

Conclusion

The appellants submit, for the reasons noted, that the Section 103(a) rejection is in error and should be reversed.

Respectfully submitted,

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APPENDIX

1. A blend of a health component and a glyceride, wherein the health component is a mixture comprising ursolic acid and oleanolic acid in a weight ratio of 1:99 to 99:1, wherein the mixture is isolated from fruit skins and contains less than 20 wt % of the natural apolar and/or low molecular weight components present in natural extracts for ursolic acid and oleanolic acid which provide an off taste to said natural extract, and wherein the blend contains 5-80 wt % of one or more components selected from mono-, di- and triglycerides as the glyceride and the glyceride part of the blend displays a solid fat content measured by NMR-pulse on a non-stabilised fat at the temperature indicated of :
5 to 90 at 5°C
2 to 80 at 20°C and
less than 15 at 35°C.

2. A blend according to claim 1 wherein the natural apolar and/or low molecular weight components that provide an off taste to the natural extract belong to the class of hydrocarbons, alcohols, fatty acids, triglycerides, ketones and carbohydrates.

5. A blended composition comprising, as component A, a blend according to claim 1, a solid fat with an N20 of more than 20 as component B and, optionally, as component C, a fat having at least 40 wt % of fatty acids with 18 C-atoms and having one to three double bonds,
component A being present in an amount of more than 0.1 wt %,
component B being present in an amount of 8 to 90 wt % and
component C being present in an amount of 0 to 85 wt %.

6. A blend according to claim 5 wherein fat B is selected from the group consisting of palm oil; palm oil fractions; coccoa butter equivalents; palm kernel oil; fractions of palm kernel oil; hardened vegetable oils such as hardened palm oil; hardened fractions of palm oil; hardened soybean oil; hardened sunflower oil; hardened

rapeseed oil; hardened fractions of soybean oil; hardened fractions of rapeseed oil; hardened fractions of sunflower oil; mixtures of one or more of these oils and interesterified mixtures thereof.

7. A blend according to claim 5 wherein fat C is selected from the group consisting of sunflower oil; olive oil; soybean oil; rapeseed oil; palm oil olein; cottonseed oil; olein fractions from vegetable oils; high oleic oil; olein fractions from vegetable oils; high oleic vegetable oils such as HOSF or HORP, fish oils; fish oil concentrates and CLA-glycerides.

8. A blend according to claim 5, wherein component A also contains isoflavones and/or flavones in amounts corresponding with 0.005 to 5 % of the total amount of ursolic acid and oleanolic acid.

9. A blend according to claim 5 wherein component A is a component isolated from fruit skins selected from the group consisting of skins from apples, pears, cranberries, cherries and prunes.

10. A food product with a fat phase comprising the blend according to claim 1.

11. A food product according to claim 10 wherein the food product is selected from the group consisting of spreads having fat contents of 10 to 90 wt %; dressings; mayonnaises; cheese; ice creams; ice cream coatings; confectionery coatings; fillings; sauces and culinary products.

12. A food product according to claim 10 or 11 wherein the food product comprises 10 to 90 wt % of a continuous fat phase.

13. A food supplement comprising the blend according to claim 1 in encapsulated form.

14. A food supplement according to claim 13, wherein the encapsulating material is selected from: sugars, carbohydrates, gums, hydrocolloids and gelatin.

17. A blend according to claim 1 wherein the weight ratio of ursolic acid to oleanolic acid is 5:95 to 95:5 and the mixture contains less than 10 wt % of the natural apolar and/or low molecular weight components.

18. A blend according to claim 1 wherein the weight ratio of ursolic acid to oleanolic acid is 15:85 to 85:15 and the mixture contains 1 to 6 wt % of the natural apolar and/or low molecular weight components.

19. A blend according to claim 4 wherein the glyceride part displays a solid fat content measured by NMR-pulse on a non-stabilised fat of less than 10 at 35°C.

20. A blended composition according to claim 5 wherein component B is a solid fat with an N20 of more than 45.

21. A blended composition according to claim 20 wherein component B is a solid fat with an N20 of more than 60.

22. A blended composition according to claim 21 wherein component A is present in an amount of 0.1 to 20 wt %, component B is present in an amount of 25 to 75 wt % and component C is present in an amount of 15 to 65 wt %.

23. A blended composition according to claim 21 wherein component A is present in an amount of 0.2 to 10 wt %, component B is present in an amount of 40 to 70 wt % and component C is present in an amount of 20 to 50 wt %.